

Amendments to the Claims

The following listing of claims replaces all prior versions of claims in the application:

- 1 (original). A monohydrochloride salt of risperidone.
- 2 (original). The salt according to claim 1, wherein the ratio of risperidone ion to chloride ion is within the range of 0.8-1.2:1.
- 3 (original). The salt according to claim 1, wherein the water solubility is less than 10 mg/ml.
- 4 (original). The salt according to claim 3, wherein the water solubility is within the range of 5 to 9 mg/ml.
- 5 (original). The salt according to claim 1 in crystalline form.
- 6 (original). The salt according to claim 5, having a purity of at least 90%.
- 7 (original). The salt according to claim 6, wherein said salt purity is at least 98%.
- 8 (original). The salt according to claim 7, wherein said salt purity is at least 99%.
- 9 (original). The salt according to claim 8, wherein said salt purity is at least 99.8%.
- 10 (original). The salt according to claim 5, wherein said salt is a crystalline risperidone hydrochloride anhydrate.
- 11 (original). The salt according to claim 10, which exhibits an x-ray powder diffraction pattern that substantially corresponds to Figure 2.
- 12 (original). The salt according to claim 5, wherein said salt is a hydrate having from about 7 to about 9.5% of water.
- 13 (original). The salt according to claim 5, wherein said salt is crystalline risperidone hydrochloride hemipentahydrate.

- 14 (original). The salt according to claim 13, which exhibits an x-ray powder diffraction pattern that substantially corresponds to Figure 4.
- 15 (original). A pharmaceutical composition comprising a risperidone monohydrochloride salt according to claim 1 and at least one pharmaceutically acceptable excipient.
- 16 (original). The pharmaceutical composition according to claim 15, wherein said composition is a solid oral dosage and said risperidone salt is contained in an amount within the range of 0.1 to 20 mg, expressed in terms of the weight of risperidone base.
- 17 (original). The pharmaceutical composition according to claim 16, wherein said risperidone salt is crystalline risperidone monohydrochloride hemipentahydrate.
- 18 (original). The pharmaceutical composition according to claim 15, wherein said composition is a liquid dosage form that contains an effective anti-psychotic amount of said risperidone salt dissolved in a liquid excipient.
- 19 (currently amended). The pharmaceutical composition according to claim 18, wherein said liquid excipient is water or a water and ethanol mixture.
- 20 (original). The pharmaceutical composition according to claim 19, which further comprises sorbitol.
- 21 (original). A process for making the salt according to claim 1, which comprises:
contacting a risperidone donor with a chloride ion donor in a solvent; and optionally precipitating a crystalline risperidone monohydrochloride salt.
- 22 (original). The process according to claim 21, wherein said risperidone donor is risperidone base or salt thereof; said chloride ion donor is hydrochloric acid or a chloride salt; and said solvent contains at least 10% water.

- 23 (original). The process according to claim 21, wherein said risperidone donor is a risperidone salt of a weak acid; said chloride ion donor is a chloride salt; said solvent is at least 90% water; and said precipitating step forms crystalline risperidone hydrochloride hemipentahydrate.
- 24 (original). The process according to claim 23, wherein said risperidone donor is risperidone acetate.
- 25 (original). The process according to claim 21, wherein said solvent is water, ethanol or a mixture thereof.
- 26 (original). A method for treating a psychotic disorder in a mammal, which comprises administering an effective anti-psychotic amount of the risperidone salt according to claim 1 to a mammal in need thereof.
- 27 (original). A risperidone monohydrochloride hemipentahydrate.
- 28 (original). A pharmaceutical composition comprising an effective anti-psychotic amount of a risperidone monohydrochloride according to claim 27 and at least one pharmaceutically acceptable excipient.
- 29 (original). A risperidone monohydrochloride salt substantially free from a risperidone dihydrochloride salt.
- 30 (original). The risperidone salt according to claim 29, wherein the amount of the risperidone dihydrochloride salt is not greater than 1% based on the total amount of risperidone salt.
- 31 (original). A pharmaceutical composition comprising an effective anti-psychotic amount of the risperidone salt according to claim 30 and at least one pharmaceutically acceptable excipient.

32 (original). The pharmaceutical composition according to claim 31, wherein said composition is a liquid dosage form.

33 (original). The pharmaceutical composition according to claim 31, wherein said composition is a solid oral dosage form.